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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GROSS, CHRISTOPHER M	
ART UNIT	PAPER NUMBER
1639	
MAIL DATE	DELIVERY MODE
07/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/694,475	TEREBA ET AL.	
	Examiner	Art Unit	
	Christopher M. Gross	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *05 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-74* is/are pending in the application.

4a) Of the above claim(s) *53,56 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-52,54,55 and 58-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/8/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Responsive to communications entered 6/5/06; 1/8/07; and 5/7/2007. Claims 1-43 have been cancelled by applicant. Claims 44-74 are pending. Claims 53,56-57 are withdrawn. Claims 44-52,54-55,58-74 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's election without traverse of: "siliceous-oxide coated magnetic particles" for the silica containing support; "genomic DNA" for the DNA [sample]; and "forensic sample" for the medium in the reply filed on 1/8/2007 is acknowledged.

Applicant states in the response entered 5/7/2007 that claims 44-52 and 54-74 read on the elected species.

During a telephone conversation with Jill Fahrlander on 7/11/2007 it was decided that a forensic sample represents a species of paper sample or swab sample (genus), therefore claims 55 and 56 do not read on the elected species of [solid-support] medium. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 53 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species of DNA [sample], there being no allowable generic or linking claim. Claims 56-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species of medium (currently support), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/8/2007.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the prior application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See Transco Prods., Inc. v. Performance Contracting, Inc., 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994) [taken from MPEP 201.01]

The instant application, filed 12/5/2003 is a DIV of 09/377,986 filed 8/20/1999 (now PAT 6673631) which is a CIP of 08/785097 filed 1/21/1997 (now PAT 6027945) Nevertheless, isolating a consistent amount of DNA from each sample, such as set forth in claim 44 is not disclosed in the earliest application (PAT 6027945).

Therefore 8/20/1999 is the date for the purposes of prior art concerning claims 44-74.

Withdrawn Objection(s) and/or Rejection(s)

The objection to claims 3-5, 21,27 and 28 being dependent on a canceled claim is hereby withdrawn in view of applicant's cancellation of the claims.

The rejection of claim 40 under 35 U.S.C. 102(b) as being anticipated by **Makowski et al.** (1997 J. Clinical Laboratory Analysis 11:87-93).is hereby withdrawn in view of applicant's cancellation the claim.

Claims 1,32 and 35-37 under 35 U.S.C. 103(a) as being unpatentable over **Hornes et al** (US Patent 5512439) in view of **Boom** et al (IDS entry 10/27/2003 - 1990 J. Clinical Microbiology 28:495-503) .is hereby withdrawn in view of applicant's cancellation the claims.

Claims 1,32-33 and 35-37 under 35 U.S.C. 103(a) as being unpatentable over **Hornes et al** (US Patent 5512439) in view of **Gocke** et al (US Patent 6156504) .is hereby withdrawn in view of applicant's cancellation the claims.

The rejection of claims 1 and 40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 16 and 27 of U.S. Patent No. 6673631 is hereby withdrawn in view of applicant's filing of a terminal disclaimer.

New Claim Rejection - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 68 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is necessitated by applicant's amendments to the claims.

Claim 68 recites vague and indefinite language in "CODIS." It is not clear as to whether the claim is directed toward genes associated with Choriodecidual inflammatory syndrome or the Federal Bureau of Investigation's Combined DNA Index System. It is recommended that the applicant amend the claim to spell out the appropriate acronym.

New Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 44-47, 49-52,54,55,58-65,66,67-74 are rejected under 35 U.S.C. 102(b) as being anticipated by **Smith et a**l (WO 98/31840 – IDS entry 1/27/2003).

This rejection is necessitated by applicant's amendments to the claims.

The claimed subject matter per claim 44 is drawn to a method for isolating a defined and consistent amount of DNA from multiple samples comprising:

(a) contacting each sample with a discrete amount of a silica-containing solid support, each sample comprising DNA in excess of the binding capacity of the discrete amount of silica-containing solid support, under conditions that allow reversible binding of the defined amount of DNA to the solid support; and

(b) separating each sample from the support to isolate a defined and consistent amount of DNA from each sample.

Claim 45 adds step (c) separating the DNA from the support.

Claims 46-49 are drawn to various types of silica particles.

Claims 50-51 are drawn to chaotropic salts.

Claim 52 is drawn to genomic DNA.

Claim 54 adds an analysis step to claim 44 (b).

Claim 59 adds a chaotropic salt to the sample

Claim 60 is drawn to various temperatures.

Claim 61 is drawn to determining at least a portion of the nucleotide sequence of the isolated DNA.

Claims 62-63 are drawn to a washing step prior to step (c) of claim 45.

Claim 64 is drawn to elution of said DNA with water.

Claim 65 is drawn to chaotropic salt concentrations.

Claim 66 is drawn to an amplification step.

Claim 67 is drawn to short tandem repeats.

Claims 69-74 are drawn to a kit for performing the above method.

Smith et al teach, throughout the document and especially the abstract methods for isolating DNA on silica magnetic particles.

Specifically, Smith et al teach in example 1 and figure 1, assessment of the binding capacity of magnetic controlled pore glass (CPG) for pGEN 3fz(x) plasmid DNA. The asymptotic binding curve of figure 1 indicates that the said plasmid DNA was added in excess of the binding capacity (i.e. 50 ug DNA per 140 mg magnetic CPG = .36 ug DNA per mg magnetic CPG) Said plasmid DNA is subsequently eluted, as show in

figure 2, according to Smith et al in what appears to be consistent and defined yield of 25 ug yield for those samples adsorbed at or above 0.36 ug/mg).

The aforementioned steps taken by Smith et al read on claims 44 and 45.

Said magnetic CPG of Smith is taken as the siliceous-oxide coated magnetic particles (elected species) of claims 46, 47 and 49.

Smith et al teach chaotropic salts such as guanidine thiocyanate on p 18, line 4, reading on claims 50,51.

Smith et al teach blood samples on p2, line 12, which is taken as inherently providing genomic DNA, such as set forth in claim 52.

Smith et al teach electrophoretic analysis of DNA samples in example 3, reading on claim 54.

Said addition of silica-containing solid support a bacterial culture, in example 4 of Smith et al is taken as providing a sample [which] comprises a solid support, as set forth in claim 55.

Said blood of Smith et al is taken as type of forensic sample, such as set forth in claim 58 (elected species).

Said chaotropic salts as well as the guanidine hydrochloride in example 1 of Smith et al read on claim 59.

On page 18, line Smith et al 30 teach incubation at temperatures less than 67 degrees C, which is in the range set forth in claim 60.

On page 17, line 4, Smith et al teach using PCR, therein using primers with a known sequence, inherently provides at least a portion of sequence of the isolated sequence, such as set forth in claim 61.

Example 4 of Smith et al utilize wash solutions comprising ethanol and a salt, reading on claims 62 and 63.

On page 20, line 22, Smith et al teach distilled water for elution, reading on claim 64.

On page 18, line 9, Smith et al teach chaotrope concentrations in the range set forth in claim 65.

Said PCR reads on the amplification of claim 66.

Smith et al teach kits in on p 8 line 22 for use with the method described above, therein reading on claim 69-74.

Claims 44-52,54,55,58,59-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kleiber et al** (WO 96/41811 – IDS entry 1/8/2007) in view of **Huber et al** (1993 Nucleic Acids Research 21:1061-1066) as evidenced by *Volgelstein et al* (1979 PNAS 615-619 – IDS entry 10/27/2003).

This rejection is necessitated by Applicant's amendment to the claims.

Kleiber et al teach, throughout the document and especially the abstract porous and poreless boro/aluminio/zirconio-silicate magnetic particles useful for DNA isolation.

Kleiber et al teach in figure 1 contacting each sample with a discrete amount of a silica-containing solid support, under conditions that allow reversible binding of the defined amount of DNA to the solid support, per claim 44 (a).

Kleiber et al teach on p 10, 3rd paragraph, separating each sample from the support per claim 44 (b).

Kleiber et al teach in figure 2, separating the DNA from the support to isolate a defined and consistent amount of DNA from each sample, such as set forth in claims 44(b) and 45. Note the eluted bands appear similar (consistent) in intensity. The amount of the corresponding amplified PCR product is defined in table 2 of Kleiber et al. .

Said porous and poreless magnetic particles of Kleiber et al are taken as the siliceous-oxide magnetic particles (elected species) of claims 46,47,48 and 49.

Kleiber et al teach chaotropic salts including guanidine thiocyanate on p 9, second paragraph, line 14, reading on claims 50 and 51.

Kleiber et al teach in example 3, the use of blood as a genomic DNA sample, reading on claim 52 (elected species). Said blood is subsequently analyzed in example 3 of Kleiber et al, as set forth in claim 54.

Said addition of silica-containing solid support to said blood, of Kleiber et al is taken as providing a sample [which] comprises a solid support, as set forth in claim 55.

Said blood is taken as type of forensic sample, such as set forth in claim 58 (elected species).

Said blood is contacted with 6 Molar guanidine HCl, a chaotropic salt at 70 degrees C on p 18, according to Kleiber et al in the second paragraph under Nucleic Acid Isolation, reading on claim 59 and in the range of claims 60 and 65.

In using primers with a known sequence, Kleiber et al inherently provide at least a portion of sequence of the isolated sequence, such as set forth in claim 61

Kleiber et al teach on p 19, line 4 washing of the magnetic particles with ethanol/water, reading on claims 62 and 63.

Kleiber et al teach elution with water in the second paragraph on p 11, last line, therein reading on claim 64.

Said amplified PCR product reads on claim 66.

SEQ ID 2 according to Kleiber comprises the nucleotide sequence GTGTGT, which giving the claims the broadest reasonable interpretation is taken as the short tandem repeat of claim 67.

Kleiber et al do not teach each sample comprising DNA in excess of the binding capacity of the discrete amount of silica-containing solid support.

Huber et al teach, throughout the document high resolution liquid chromatography of DNA fragments on poly(styrene-divinylbenze) (PS-DVB) particles.

Specifically, Huber et al teach in figure 9 and p1066 third paragraph under 'Quantitation of PCR Products' application of increasing amounts of 404 bp PCR product to a PS-DVB column and indicate a loading capacity of 0.5 ug whereas up to 5 ug may be applied for semipreparative purposes.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to measure the DNA binding capacity of the porous and poreless boro/aluminio/zirconio-silicate-borosilicate magnetic particles per Kleiber et al using the method reported by Huber et al.

One of ordinary skill in the art would have been motivated to use the measurement technique reported by Huber et al in regard to the DNA binding capacity

of the porous and poreless boro/aluminio/zirconio-silicate magnetic particles per Kleiber et al because it would provide an upper limit for DNA binding and better characterize the boro/aluminio/zirconio-silicate magnetic particles.

Evidence provided Volgelstein et al indicate the need for discerning the DNA binding capacity of solid supports. As illustrated in figure 1A, Vogelstein et al contrast the DNA binding capacity of various types of silica containing materials including large glass particles, medium flint glass and flint glass powder.

One of ordinary skill in the art would have had a reasonable expectation of success in measuring the DNA binding capacity of the porous and poreless boro/aluminio/zirconio-silicate magnetic particles of Kleiber et al with the protocol advocated by Huber et al because both represent a manner of solid-phase extraction of DNA. Thus, the technique of Huber et al lies well within the scope of teaching of Kleiber et al.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

cg

/Jon E. Epperson/
Primary Examiner, AU 1639